

REMARKS

At the outset, the undersigned would like to thank Examiner Epps-Ford for her helpful comments during an interview conducted on November 4, 2004. The substance of the interview is incorporated herein.

Upon entry of the instant amendment, claims 12-13, 16-21, 25-27, 32-37, 41-52, and 54-83 are pending in the instant application. Claims 33, 44-49, 51, and 65-67 have been amended. Claims 78-83 have been added. Support for the amendments can be found, for example, on page 16, lines 16-18 of the Substitute Specification filed on June 27, 2003.

Rejections Under 35 U.S.C. §102(e) over U.S. Patent No. 6,482,803 to Roth

The Examiner rejected claims 12-13, 16-21, 26, 32-37, and 42-45 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,482,803 (Roth). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Roth does not disclose replacement nucleic acids that have been altered so that the suppression effector cannot bind to and/or cleave the replacement nucleic acid. Although Roth describes replacement nucleic acids that can have alternative codons to wild-type nucleic acids, Roth does not specifically disclose altering wobble bases in codons to avoid cleavage by his ribozyme. Roth's teaching of using alternative codons in a replacement nucleic acid is not connected to how Roth would prevent a ribozyme from targeting a replacement nucleic acid. That is because absent one statement that Roth's ribozymes may be designed to target a specific mutated codon in p53 mRNA, Roth's disclosure is completely limited to the use of ribozymes that cleave intron/exon splice junctions. Roth therefore does not provide any teaching or guidance as to how a replacement nucleic acid could be designed to avoid cleavage by his ribozyme, because the replacement nucleic acid taught by Roth simply does not have the ribozyme target site because it is a cDNA and does not have splice junctions. Roth therefore could not have anticipated or suggested Applicants' invention.

Since Roth does not identically disclose each and every element of Applicants' claims it is not a proper reference under 35 U.S.C. §102(e). Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 12, 5, 41-44, 51, 62-64, 70-71, 73, and 75-77 under 35 U.S.C. §112, first paragraph, contending that the application lacks evidence that a nucleic acid or PNA could be used to specifically target a mutant allele and not suppress a replacement nucleic acid that differs only by one nucleotide. Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Applicants' claims recite replacement nucleic acids that differ from the RNA encoding the mutant allele by at least one degenerate/wobble nucleotide. For example, Applicants' replacement nucleic acids may differ in every wobble base in the suppression effector binding region, in which case there would be only 67% complementarity between the suppression effector and the replacement nucleic acid. An antisense nucleic acid or PNA would not bind to such a mismatched nucleic acid, or would bind much less effectively, under physiological conditions. Alternatively, the replacement nucleic acid may differ in just one wobble base from the target nucleic acid in the suppression effector binding region, for example, within a ribozyme NUX cleavage site. A replacement nucleic acid could also differ by 2, 3, 4 or any number of wobble bases in order to avoid binding to and/or cleavage by a suppression effector, depending, for example, upon the length and composition of the suppression effector. Applicants are not required to demonstrate that any conceivable embodiment is operative, just that there are operative embodiments within the scope of the claims. Applicants therefore respectfully request that the rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph

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The Examiner rejected claims 46-49, and 65-67 under 35 U.S.C. §112, first paragraph, contending that the claims encompass both deoxyribonucleotides and ribonucleotides. Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Not in acquiescence of the rejection but in order to expedite allowance of the claims, Applicants have amended the claims to recite "ribonucleotide" rather than "nucleotide".

Applicants respectfully request that the rejection be reconsidered and withdrawn.

Double Patenting

The Examiner provisionally rejected claims 12-13, 16-21, 25-27, 32-37, 41-52, and 54-77 under the judicially created doctrine of obviousness-type double patenting over claims 1-23 of co-pending U.S. Serial No. 10/651,754.


Applicants respectfully request that the provisional rejection be held in abeyance until either the instant Application or U.S. Serial No. 10/651,754 issues.

CONCLUSION

Applicants respectfully urge that all claims are in condition for allowance and request prompt and favorable action on the instant application. If the Examiner believes that a telephonic interview with the undersigned would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned at (617) 338-2952.

Respectfully submitted,

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